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Of Counsel

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
IN RE: FOSAMAX PRODUCTS LIABILITY
LITIGATION – MDL NO. 1789

ANNE M. LUA,

X

Plaintiff,

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V.

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MERCK & CO., INC.;
PROCTER & GAMBLE
PHARMACEUTICALS, INC.;
SANOFI-AVENTIS US, INC.; and
SANOFI-AVENTIS US, L.L.C.,

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Defendants.

CIVIL ACTION NO. 1:09-CV-4358

ANSWER

Procter & Gamble Pharmaceuticals, Inc. (“P&G”), sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. answer Plaintiff Anne M. Lua’s (“Plaintiff”) Original Complaint (“Complaint”) as follows:

ANSWER

I. JURISDICTION AND VENUE

1. In answer to paragraph 1 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that jurisdiction is proper in federal court. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. further admit that Plaintiff, upon information and belief, and P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. are citizens of different states. Although they deny Plaintiff is entitled to any damages whatsoever, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that, upon information and belief, the amount in controversy appears to be greater than \$75,000.

2. The allegations in paragraph 2 of the Complaint state legal conclusions and therefore no response is required from P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc.. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

II. PARTIES

3. In answer to paragraph 3 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

4. The allegations in paragraph 4 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

5. The allegations in paragraph 5 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them.

To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein

6. The allegations in paragraph 6 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

7. The allegations in paragraph 7 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

8. In answer to paragraph 8 of the Complaint, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendant P&G denies any remaining allegations.

9. In answer to paragraph 9 of the Complaint, Defendants sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that they are Delaware corporations with their principal place of business in New Jersey. Defendants sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

10. In answer to paragraph 10 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold

Actonel in the United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 10.

11. In answer to paragraph 11, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel is a brand name of risedronate sodium, a bisphosphonate, and that it was approved by the FDA for prevention and treatment of osteoporosis. Defendant P&G further admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S. L.L.C. further admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S., Inc. further admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 11.

12. In answer to paragraph 12 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that they conduct business in the state of Washington. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

13. In answer to paragraph 13 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that they conduct business in the state of Washington. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

III. SUMMARY OF THE CASE

14. The allegations in paragraph 14 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S.,

Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

15. The allegations in paragraph 15 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

16. The allegations in paragraph 16 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

17. The allegations in paragraph 17 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

18. The allegations in paragraph 18 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

19. The allegations in paragraph 19 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

20. The allegations in paragraph 20 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

21. In answer to paragraph 21 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel was approved by the FDA for prevention and treatment of osteoporosis. Defendant P&G further admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant P&G denies the remaining allegations contained in paragraph 21. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. Defendants sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 21.

22. In answer to paragraph 22 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant P&G denies the remaining allegations contained in paragraph 22. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold Actonel in the

United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. Defendants sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 22.

23. In answer to paragraph 23 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

24. In answer to paragraph 24 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

25. In answer to paragraph 25 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

26. In answer to paragraph 26 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

27. In answer to paragraph 27 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

28. In answer to paragraph 28 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

29. In answer to paragraph 29 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

30. In answer to paragraph 30 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

31. In answer to paragraph 31 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc., admit that this is a civil action for alleged damages suffered by Plaintiff. However, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny that Plaintiff suffered any damages as a result of her allegedly being prescribed and her alleged ingestion of the medication Actonel. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 31.

IV. FACTUAL BACKGROUND

32. The allegations in paragraph 32 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

33. The allegations in paragraph 33 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

34. In answer to paragraph 34 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold

Actonel in the United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. Defendants sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 34.

35. In answer to paragraph 35 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel is a brand name of risedronate sodium, and that it was approved by the FDA for prevention and treatment of osteoporosis.

36. In answer to paragraph 36 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel is a brand name of risedronate sodium, a bisphosphonate, and that it was approved by the FDA for prevention and treatment of osteoporosis. As to the remaining allegations in paragraph 36, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

37. In answer to paragraph 37 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel is a nitrogen-containing bisphosphonate, and P&G admits that etidronate and clodronate are non-N-containing bisphosphonates. As to the remaining allegations in paragraph 37, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

38. In answer to paragraph 38 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel is a nitrogen-containing bisphosphonate. As to the remaining allegations in paragraph 38, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S.,

Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

39. The allegations in paragraph 39 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

40. The allegations in paragraph 40 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

41. The allegations in paragraph 41 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

42. The allegations in paragraph 42 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

43. The allegations in paragraph 43 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

44. The allegations in paragraph 44 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

45. The allegations in paragraph 45 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

46. The allegations in paragraph 46 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

47. The allegations in paragraph 47 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S.,

Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

48. The allegations in paragraph 48 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

49. The allegations in paragraph 49 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

50. The allegations in paragraph 50 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

51. The allegations in paragraph 51 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the FDA review speaks for itself. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

52. In answer to paragraph 52 of the Complaint, as it applies to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc., P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

53. The allegations in paragraph 53 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

54. The allegations in paragraph 54 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

55. The allegations in paragraph 55 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

56. The allegations in paragraph 56 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them.

To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

57. The allegations in paragraph 57 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

58. The allegations in paragraph 58 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

59. The allegations in paragraph 59 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

60. The allegations in paragraph 60 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

61. The allegations in paragraph 61 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

62. The allegations in paragraph 62 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

63. The allegations in paragraph 63 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

64. The allegations in paragraph 64 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

65. The allegations in paragraph 65 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S.,

Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

66. The allegations in paragraph 66 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

67. In answer to paragraph 67 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

68. In answer to paragraph 68 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein. Because Plaintiff has failed to specifically identify the study referred to in paragraph 68, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc., after reasonable investigation, lack knowledge and information sufficient to form a belief as to the truth of such allegations and therefore deny the allegations contained therein.

69. In answer to paragraph 69 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

70. In answer to paragraph 70 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

71. In answer to paragraph 71 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

72. In answer to paragraph 72 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

73. In answer to paragraph 73 of the Complaint, as it applies to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc., P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that reports of osteonecrosis of the jaw purportedly associated with use of Actonel have been reported. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

74. In answer to paragraph 74 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

75. In answer to paragraph 75 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

76. In answer to paragraph 76 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

77. In answer to paragraph 77 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

78. In answer to paragraph 78 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

79. In answer to paragraph 79 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

80. The allegations in paragraph 80 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

81. In answer to paragraph 81 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

82. In answer to paragraph 82 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

83. In answer to paragraph 83 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

84. In answer to paragraph 84 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

85. In answer to paragraph 85 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

86. In answer to paragraph 86 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

87. In answer to paragraph 87 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

88. In answer to paragraph 88 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

89. In answer to paragraph 89 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNTS

COUNT I: NEGLIGENCE

90. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

91. The allegations in paragraph 91 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

92. The allegations in paragraph 92 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

93. The allegations in paragraph 93 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S.,

Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

94. The allegations in paragraph 94 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

95. The allegations in paragraph 95 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

96. The allegations in paragraph 96 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

97. In answer to paragraph 97 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations.

98. In answer to paragraph 98 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that they had a duty to comply with all applicable law, which they did. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations contained in paragraph 98.

99. In answer to paragraph 99 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein, including all sub-parts.

100. In answer to paragraph 100 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

101. In answer to paragraph 101 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

102. In answer to paragraph 102 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT II: STRICT LIABILITY

103. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

104. The allegations in paragraph 104 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

105. The allegations in paragraph 105 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

106. The allegations in paragraph 106 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

107. The allegations in paragraph 107 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

108. The allegations in paragraph 108 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

109. The allegations in paragraph 109 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

110. The allegations in paragraph 110 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

111. The allegations in paragraph 111 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

112. The allegations in paragraph 112 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

113. The allegations in paragraph 113 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

114. The allegations in paragraph 114 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

115. The allegations in paragraph 115 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

116. In answer to paragraph 116 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S. L.L.C. admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis U.S., Inc. admits that sanofi-aventis U.S. L.L.C. is the entity that marketed, distributed and sold Actonel in the United States. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the remaining allegations.

117. In answer to paragraph 117 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

118. In answer to paragraph 118 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

119. In answer to paragraph 119 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

120. In answer to paragraph 120 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

121. In answer to paragraph 121 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

122. In answer to paragraph 122 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations. By way of further answer, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the Actonel labeling and package inserts were approved by the FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

123. In answer to paragraph 123 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

124. In answer to paragraph 124 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

125. In answer to paragraph 125 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

126. In answer to paragraph 126 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

127. In answer to paragraph 127 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT III: BREACH OF EXPRESS WARRANTY

128. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

129. The allegations in paragraph 129 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

130. The allegations in paragraph 130 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

131. The allegations in paragraph 131 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

132. The allegations in paragraph 132 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

133. The allegations in paragraph 133 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

134. The allegations in paragraph 134 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

135. The allegations in paragraph 135 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

136. In answer to paragraph 136 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

137. In answer to paragraph 137 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

138. In answer to paragraph 138 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

139. In answer to paragraph 139 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

140. In answer to paragraph 140 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

141. In answer to paragraph 141 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

142. In answer to paragraph 142 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT IV: BREACH OF IMPLIED WARRANTY

143. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

144. The allegations in paragraph 144 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

145. The allegations in paragraph 145 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

146. The allegations in paragraph 146 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

147. The allegations in paragraph 147 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

148. The allegations in paragraph 148 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

149. The allegations in paragraph 149 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

150. The allegations in paragraph 150 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

151. The allegations in paragraph 151 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

152. The allegations in paragraph 152 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

153. In answer to paragraph 153 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel was approved by the FDA for the prevention and treatment of osteoporosis. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

154. In answer to paragraph 154 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. admit that Actonel was approved by the FDA for the prevention and treatment of osteoporosis. Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny any remaining allegations.

155. In answer to paragraph 155 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

156. In answer to paragraph 156 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

157. In answer to paragraph 157 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

158. In answer to paragraph 158 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and therefore deny the allegations contained therein.

159. In answer to paragraph 159 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

160. In answer to paragraph 160 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

161. In answer to paragraph 161 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT V: FRAUDULENT MISREPRESENTATION

162. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

163. The allegations in paragraph 163 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

164. The allegations in paragraph 164 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

165. The allegations in paragraph 165 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

166. The allegations in paragraph 166 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

167. The allegations in paragraph 167 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

168. The allegations in paragraph 168 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

169. The allegations in paragraph 169 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

170. The allegations in paragraph 170 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

171. The allegations in paragraph 171 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

172. The allegations in paragraph 172 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

173. In answer to paragraph 173 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein, including all sub-parts.

174. In answer to paragraph 174 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

175. In answer to paragraph 175 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

176. In answer to paragraph 176 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

177. In answer to paragraph 177 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

178. In answer to paragraph 178 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

179. In answer to paragraph 179 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

180. In answer to paragraph 180 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

181. In answer to paragraph 181 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

182. In answer to paragraph 182 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT VI: FRAUDULENT CONCEALMENT

183. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

184. The allegations in paragraph 184 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

185. The allegations in paragraph 185 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

186. The allegations in paragraph 186 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

187. The allegations in paragraph 187 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

188. The allegations in paragraph 188 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis

U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

189. The allegations in paragraph 189 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

190. The allegations in paragraph 190 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

191. The allegations in paragraph 191 of the Complaint are not directed to P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and therefore require no response from them. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

192. In answer to paragraph 192 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein, including all sub-parts.

193. In answer to paragraph 193 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

194. In answer to paragraph 194 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

195. In answer to paragraph 195 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

196. In answer to paragraph 196 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

197. In answer to paragraph 197 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

198. In answer to paragraph 198 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

199. In answer to paragraph 199 of the Complaint, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

COUNT VII: JOINT AND SEVERAL LIABILITY

200. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 89 above.

201. The allegations in paragraph 201 state legal conclusions and therefore no response is required from P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc.. To the extent a response is required, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny the allegations contained therein.

GLOBAL PRAYER FOR RELIEF

202. Plaintiff's "Global Prayer for Relief" section of the Complaint does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny each and every allegation and assertion listed under the "Global Prayer for Relief" section of Plaintiff's Complaint and deny that Plaintiff is entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

203. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. to determine all of their legal, contractual and equitable rights, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery proceedings in this case and hereby reserve the right to amend and/or supplement this answer to assert any such defense at a future time and in conformity with the Federal Rules of Civil Procedure.

FIRST AFFIRMATIVE DEFENSE

204. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

205. Any drug for which P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. were responsible at the time of the occurrences or injuries allegedly suffered by Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and it was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the drug at issue in this case were legally adequate warnings and instructions.

THIRD AFFIRMATIVE DEFENSE

206. Plaintiff's claims are barred in whole or in part because P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. provided adequate "direction or warnings" as to the use of any of its drugs within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

FOURTH AFFIRMATIVE DEFENSE

207. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. assert the applicability of comment k of the Restatement (Second) of Torts § 402A, which bars Plaintiff's claims in this lawsuit.

FIFTH AFFIRMATIVE DEFENSE

208. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. deny that Plaintiff used any drug manufactured or marketed by P&G and sanofi-aventis U.S. L.L.C. as alleged in Plaintiff's Complaint.

SIXTH AFFIRMATIVE DEFENSE

209. Any and all damages alleged by Plaintiff may have been caused by misuse of the drug at issue, failure to use the drug properly, and/or alteration or negligent use of the drug.

SEVENTH AFFIRMATIVE DEFENSE

210. If Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

211. The occurrences and injuries alleged by Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. had no control and for whom they are not responsible.

NINTH AFFIRMATIVE DEFENSE

212. Plaintiff's claims may be barred by negligence/fault of others, and/or by the assumption of risks, if any, inherent in the alleged use of the drug at issue by Plaintiff and/or the

treating physicians and/or other health care providers. Defendants thus rely on the doctrine of comparative fault with regard to any negligence/fault of Plaintiff and any non-party tortfeasors.

TENTH AFFIRMATIVE DEFENSE

213. If Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff and/or of third parties, not from any negligence or breach of duty by P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc..

ELEVENTH AFFIRMATIVE DEFENSE

214. The occurrences and injuries alleged by Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrences and injuries alleged by Plaintiff. Moreover, the occurrences and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any alleged breach of legal duty on the part of P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and the occurrences and injuries alleged by Plaintiff, and thereby become the immediate and/or sole cause and/or sole proximate cause of such occurrences and injuries, relieving P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. of liability to Plaintiff or any other parties.

TWELFTH AFFIRMATIVE DEFENSE

215. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or act of God.

THIRTEENTH AFFIRMATIVE DEFENSE

216. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc..

FOURTEENTH AFFIRMATIVE DEFENSE

217. If the Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses for which P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. are not responsible.

FIFTEENTH AFFIRMATIVE DEFENSE

218. The FDA has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. The drug at issue in this case was approved by the FDA pursuant to such applicable statutes and regulations and, pursuant to such, could only be used pursuant to the prescription of a licensed prescriber. The labeling for the drug at issue was also approved by the FDA and the marketing was conducted in conformity with the FDA's rules and regulations. Actonel was subject to and received pre-market approval by the Food & Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301. To the extent Plaintiff asserts claims based on P&G's, sanofi-aventis U.S. L.L.C.'s and sanofi-aventis U.S., Inc.'s adherence to and compliance with applicable federal laws, regulations and rule, such claims are preempted.

SIXTEENTH AFFIRMATIVE DEFENSE

219. Plaintiff cannot recover because the drug at issue was designed and/or made in accordance with the state of the art at the relevant time.

SEVENTEENTH AFFIRMATIVE DEFENSE

220. P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. state that the benefits of the drug at issue outweigh the risks, if any, which may be attendant to its use.

EIGHTEENTH AFFIRMATIVE DEFENSE

221. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations.

NINETEENTH AFFIRMATIVE DEFENSE

222. Plaintiff's claims are barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

TWENTIETH AFFIRMATIVE DEFENSE

223. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

TWENTY-FIRST AFFIRMATIVE DEFENSE

224. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

TWENTY-SECOND AFFIRMATIVE DEFENSE

225. Actonel is a prescription pharmaceutical that was available only upon the prescription of a licensed physician, and persons other than P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc., including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediaries between P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. and Plaintiff. Any claims against P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. accordingly are barred in whole or in part by the learned

intermediary doctrine because P&G's, sanofi-aventis U.S. L.L.C.'s and sanofi-aventis U.S., Inc.'s only obligation is to warn the Plaintiff's prescribing physician, and that obligation was fulfilled.

TWENTY-THIRD AFFIRMATIVE DEFENSE

226. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Third) of Torts §§ 2, 4, and 6.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

227. Plaintiff's claims relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

228. This case is more appropriately brought in a different venue.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

229. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, P&G's, sanofi-aventis U.S. L.L.C.'s and sanofi-aventis U.S., Inc.'s liability, if any, should be reduced accordingly.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

230. Plaintiff's claims are barred in whole or in part because Plaintiff has failed to mitigate the alleged damages.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

231. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended functions of Actonel.

TWENTY-NINTH AFFIRMATIVE DEFENSE

232. Plaintiff's claims are barred in whole or in part because Defendants P&G's, sanofi-aventis U.S. L.L.C.'s and sanofi-aventis U.S., Inc.'s conduct conforms with medical knowledge.

THIRTIETH AFFIRMATIVE DEFENSE

233. At all times relevant herein, any drug which is the subject matter of this action manufactured and distributed by P&G and sanofi-aventis U.S. L.L.C. in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-FIRST AFFIRMATIVE DEFENSE

234. To the extent there were any risks associated with the use of the drug which is the subject matter of this action which P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. knew or should have known and which gave rise to a duty to warn, P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-SECOND AFFIRMATIVE DEFENSE

235. Plaintiff has not sustained any recoverable loss of property or money.

THIRTY-THIRD AFFIRMATIVE DEFENSE

236. Plaintiff has not suffered any actual injury or damages.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

237. Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

238. Plaintiff's claims of fraud are not pleaded with the required particularity.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

239. Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

240. Plaintiff lacks standing because Plaintiff has suffered no damages and no injury-in-fact.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

241. With respect to each and every purported cause of action, the acts of P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. were at all times done in good faith and without malice.

THIRTY-NINTH AFFIRMATIVE DEFENSE

242. Defendants deny that they have been guilty of any conduct which warrants the issue of punitive damages being submitted to a jury.

FORTIETH AFFIRMATIVE DEFENSE

243. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

FORTY-FIRST AFFIRMATIVE DEFENSE

244. To the extent that Plaintiff seeks punitive damages, such claim is barred because Actonel and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FORTY-SECOND AFFIRMATIVE DEFENSE

245. Any award of punitive damages to Plaintiff in this case would be in violation of the constitutional safeguards provided to Defendants under the Constitution of the United States of America.

FORTY-THIRD AFFIRMATIVE DEFENSE

246. With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decision of BMW of No. America v. Gore, 116 U.S. 1589 (1996)(as extended by Cooper Indus. v. Leatherman Tool Group, 2001 W.L. 501732 (U.S. May 14, 2001) and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S. Ct. 1513 (2003)).

JURY DEMAND

P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. hereby demand a trial by jury on all of Plaintiff's claims.

WHEREFORE, Defendants P&G, sanofi-aventis U.S. L.L.C. and sanofi-aventis U.S., Inc. pray for judgment as follows:

1. That Plaintiff take nothing by her Complaint;
2. For such other and further relief as the court may deem just and proper.

Dated: July 1, 2009

Respectfully submitted,

By: 

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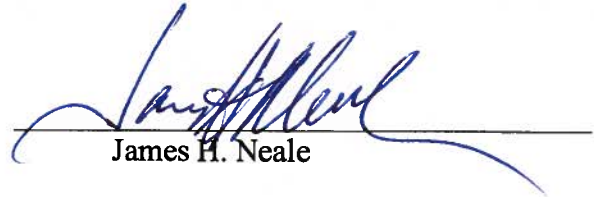
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CERTIFICATE OF SERVICE

I certify that this document was served by U.S. Mail on July 7, 2009 on the following counsel:



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